DRAFT GUIDANCE OF EFSA

EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil¹

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ABSTRACT

EFSA was asked by the Commission to prepare a Guidance of EFSA for evaluating laboratory and field dissipation studies to obtain degradation rate parameters (DegT50 values) of active substances of plant protection products and transformation products of these active substances in soil. This EFSA Guidance Document provides guidance for users on how to obtain DegT50 values when performing risk assessments according to Regulation EC no 1107/2009 of the European Parliament and the Council.

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KEY WORDS

soil degradation, Kom, Koc, Crop Interception, Plant Wash-off

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SUMMARY

EFSA was asked by the Commission to prepare a Guidance of EFSA for evaluating laboratory and field dissipation studies to obtain degradation rate parameters (DegT50 values) of active substances of plant protection products and transformation products of these active substances in soil. This EFSA Guidance Document provides guidance for users on how to obtain DegT50 values to be used in exposure assessment when performing risk assessments according to Regulation EC no 1107/2009 of the European Parliament and the Council.

A number of Member States expressed interest in a revision of the current SANCO Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000) during a general consultation of Member States on Guidance Documents in answer to a request by EFSA sent via the Standing Committee on the Food Chain and Animal Health. Furthermore the previous PRAPeR Unit (now Pesticides Unit) noted that the existing SANCO Guidance Document (SANCO/9188VI/1997 of 12 July 2000) needed to be updated.

Forum for the Co-ordination of pesticide fate models and their Use (FOCUS, 1997) developed the first guidance at EU level for exposure assessment in soil which did not include recommendations on how to estimate degradation rate parameters. FOCUS (2006) developed detailed guidance on estimating degradation and dissipation rate parameters from laboratory and field studies. The PPR Panel produced an Opinion for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil (EFSA, 2010).


The Guidance Document contains guidance on:

- Deriving DegT50 values for use in exposure assessment
- Design of field studies for obtaining Deg50 values in soil
- Use of geomean Kom and Koc
- Use of updated Crop Interception values
- Handling of substance processes on crop surface
- Worked examples on how to use this guidance
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BACKGROUND AS PROVIDED BY THE COMMISSION

During a general consultation of Member States on needs for updating existing Guidance Documents and developing new ones, a number of EU Member States (MSs) requested a revision of the SANCO Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000). The consultation was conducted through the Standing Committee on the Food Chain and Animal Health.

Based on the Member State responses and the Opinions prepared by the PPR Panel (EFSA 2010 and 2012) the Commission tasked EFSA to prepare a Guidance of EFSA for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil in a letter of 31 July 2012. EFSA accepted this task in a letter to the Commission dated 9 October 2012. The Commission requests this scientific and technical assistance from EFSA according to Article 31 of Regulation (EC) no 178/2002 of the European Parliament and of the Council.

Following public consultations on the Opinion (EFSA, 2010), Member States and other stakeholders requested “an easy to use Guidance Document” to facilitate the use of the proposed guidance and methodology for the evaluation of PPPs according to Regulation (EC) No 1107/2009.

Once this Guidance Document is delivered, the Commission will initiate the process for the formal use of the Guidance Documents within an appropriate time frame for applicants and evaluators.

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

EFSA, and in particular the Pesticides Unit, is asked by the Commission (DG SANCO) to draft an EFSA Guidance Documents as mentioned below:

1) EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil.

The EFSA Guidance Documents should respect the science proposed and methodology developed in the adopted PPR opinion mentioned in this document (EFSA 2010).

EFSA is requested to organise public consultations on the draft Guidance Documents, to ensure the full involvement of Member States and other stakeholders. To support the use of the new guidance, EFSA is requested to organise training of Member State experts, applicants and other relevant stakeholders.

CONTEXT OF THE SCIENTIFIC OUTPUT

To address the Terms of References as provided by the Commission.
1. Introduction

During work conducted by the PPR Panel of EFSA to revise the Guidance Document on Persistence of Pesticides in Soil (EC, 2000), EFSA published a scientific opinion on evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil (herein referred to as EFSA DegT50 opinion, (EFSA, 2010). This document builds on the scientific opinion to provide practical guidance to regulatory specialists involved with EU environmental exposure assessment of plant protection products for derivation of these values.

DegT50 values of pesticide active substances and their transformation and reaction products (hereafter referred to as ‘metabolites’) in soil are critical information used in plant protection product risk assessment. The values are used in the current FOCUS modelling frameworks for estimating groundwater and surface water exposure levels. In addition, they are used in the soil exposure scenarios developed by EFSA as a result of the revision of the Guidance Document on Persistence of Pesticides in Soil.

Guidance on EU groundwater modelling can be found at FOCUS (2009)
Guidance on EU surface water modelling can be found at FOCUS (2001)
Guidance on EU soil exposure modelling in preparation can be found at EFSA (2014)

The output of these exposure models is often very sensitive to the DegT50 value used as an input value. In addition, as the models used in the exposure assessment methodology expressly require a DT50 which represents true degradation in the bulk soil matrix, it is important that calculation of soil DT50 for use in the model excludes other loss processes which could influence the observed disappearance in laboratory or field studies.

Therefore, the aims of this guidance are:

i) to provide methods to derive the bulk soil matrix DegT50 from individual laboratory and field dissipation studies,

ii) explain how to determine whether the databases of DegT50 values from laboratory and field studies can be treated as separate databases or whether they should be pooled

iii) provide guidance on selecting the appropriate input value for use in exposure modelling.

Whilst historically work on DegT50 in soil was initiated in relation to new guidance on soil exposure, the DegT50 values calculated using this guidance should be used in EU ground- and surface water exposure assessment, as the soil degradation parameters required by the models are used in the exposure assessment framework.
2. Derivation of DegT50 from laboratory and field dissipation studies

2.1. Background

The derivation of decline rates for active substances and metabolites from soil studies is addressed in detail in the FOCUS Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (herein referred to as FOCUS Kinetics, FOCUS (2006)). This guidance document does not attempt to change the methodology recommended by FOCUS Kinetics, but gives further advice on study conduct and pre-processing of data prior to calculation. Use of this guidance assumes a working knowledge and understanding of the principles of the FOCUS Kinetics guidance.

2.2. Laboratory studies

The primary laboratory study used for derivation of DegT50 in soil is the aerobic route and rate of degradation study conducted under dark conditions with radiolabelled test substance; current EU data requirements recommend that such studies are conducted in accordance with the OECD 307 study guideline. The provision of such studies is a standard data requirement for the vast majority of active substances, excluding those where there is no soil exposure as a result of use. In most cases, the primary route of decline of the applied substance and metabolites/degradation products in this study is by microbial and/or chemical processes which represent degradation in the bulk soil matrix. In such cases, the derivation of DegT50 for an individual soil is achieved following FOCUS Kinetics guidance. In some cases, disappearance can be influenced by other routes of loss, principally volatilisation; photolysis is excluded as the study is conducted under dark conditions. Volatilisation should be accounted for in the study design by appropriate trapping methods allowing the volatilisation losses to be quantified. This route of loss can subsequently be accounted for in the kinetic evaluation. FOCUS Kinetics guidance should be followed in accounting for such losses and other experimental artefacts.

2.3. Field studies

Current EU data requirements recommend use of NAFTA guidance on the conduct of terrestrial field dissipation studies (NAFTA, 2006). At the time of writing, an OECD guidance document on the conduct of these studies to take into account generation of data for derivation of DegT50 was in preparation.

Derivation of DegT50 from field dissipation studies is complicated by a number of factors. The overall rate of decline is influenced by the fact that factors such as volatilisation, soil surface photolysis, leaching out of the sampled soil layers and uptake into plants can significantly influence the disappearance of the applied substance from the sampled soil layers in addition to degradation in the bulk matrix. As a result, in many cases the initial decline of applied substance can be more rapid followed by a slower rate of decline. In addition, the influence of soil photolysis and leaching can affect the formation and decline profile of any metabolites/degradation products formed. Rates of decline for the applied substance (and formation and decline for metabolites) are also influenced by variations in soil temperature and moisture. Therefore the derivation of bulk soil DegT50 values for use in exposure modelling must take these other processes and variations into account. FOCUS Kinetics provides guidance on assessing whether the field dissipation study is suitable for calculation of DegT50 by assessing likely impact of these other loss processes, and subsequently details procedures by which the effects of varying temperature and moisture may be normalised to derive a DegT50 at standard temperature and moisture conditions of 20°C and pF2 field moisture capacity (recommendations are found in Chapter 9 of FOCUS Kinetics guidance). However the approach...
described in chapter 9 of FOCUS kinetics still leaves uncertainty over the true representation of bulk soil matrix degradation processes within the calculated DT50.

Appropriate design of the field dissipation study can greatly help in minimising the ‘surfaces processes’ of volatilisation and soil surface photolysis and plant uptake. Section 2.3.1 makes recommendations for study design which will reduce the influence of these processes on the calculation of DegT50.

2.3.1. Tailored DegT50 field studies

When designing an experiment to estimate DegT50 in bulk topsoil, all processes that can affect the fate of the test chemical, except the formation of transformation products by chemical or microbial processes or not extracted residues, (such as leaching out of the microbially active top 30 cm soil layers, volatilisation, soil surface photolysis, runoff and plant uptake) should be minimised as far as possible. Therefore field plots where the aim of the experiment is to get a best estimate of DegT50 need an experimental design that aims to exclude the influence of surface processes and leaching as far as is practical. More detailed guidance on designing new DegT50 experiments is outlined in Appendix A. When experiments have been carried out following the recommendations in Appendix A, kinetic fitting of the experimental results should be carried out following FOCUS kinetics guidance (FOCUS 2006).

As the DegT50 study design deliberately attempts to exclude the influence of surface processes and leaching, it must be borne in mind that the DegT50 study may not be appropriate to obtain endpoints for comparison against the field persistence criteria in the European Pesticides legislation. This is because the field persistence criteria (for use in ecotoxicological risk assessment for soil organisms) can potentially allow the inclusion of dissipation processes other than bulk topsoil biotic and abiotic degradation.

In contrast, it is possible that DegT50 values obtained from field dissipation studies may be appropriate for use in hazard assessment in relation to POP, PBT and vPvB criteria within European Pesticides legislation. However, as the study design for obtaining DegT50 in the field specifically excludes the influence of photolysis, the relevance of field-derived DegT50 values for POP, PBT and vPvB assessment may be limited where soil surface photolysis might be expected to be a significant route of degradation for a substance.

It should also be noted that where losses other than chemical/microbial transformation processes or formation of non-extractable residues⁴ have been minimised, it should also be possible to calculate DegT50 for any transformation products formed in the study.

2.3.2. Existing field studies not tailored for DegT50 (legacy studies)

The EFSA DegT50 opinion also advised of a procedure to be taken where surface processes have not been minimised. This involves consideration of degradation rate of the decline curve after cumulative rainfall of 10mm has occurred. This procedure is useful for calculation of bulk soil matrix DegT50 for the applied substance. However, as it is possible that soil photolysis may have influenced degradation

⁴ non-extractable residues means chemical species originating from active substances contained in plant protection products used in accordance with good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues or the nature of the soil matrix. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products. Definition from Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.
before this point, it is possible that the observed metabolite residues will also have been influenced by photolytic processes. Therefore, where this procedure has been applied for the active substance, it is considered that kinetic parameters for metabolites may not be wholly reflective of bulk soil matrix degradation applying to metabolites. In addition, the exclusion of initial data points for the metabolite is likely to create significant problems for any calculations attempted for the metabolites. Therefore a study should not be used for calculating the DegT50 of any primary metabolite that is formed before 10 mm of rainfall has occurred or secondary metabolites formed later when its precursor was formed before 10 mm of rainfall.

The recommended approach is to conduct a time-step normalisation procedure on the data set (as described in FOCUS Kinetics Chapter 9) and then to apply the following decision-making flow charts to derive the most appropriate kinetic model to the dataset and thus derive the DegT50. The initial approach is to the use the flow chart in Figure 1 which uses DFOP kinetics.

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**Figure 1:** Flow chart for assessment of results of field dissipation studies after analysis with the DFOP model. The numbers 1 to 8 act as references to the corresponding boxes in the main text. The test of the accuracy in box 8 should be done by following procedures similar to those recommended by FOCUS Kinetics.

Box 1 in Figure 1 checks whether the decline in laboratory studies shows a lag-phase or indicates a slowing down of the decline due to long-term sorption kinetics. A lag phase is reasonably easy to interpret, however, long-term sorption kinetics may be harder to recognise and requires a specific
assessment to determine whether this occurs in individual laboratory incubations. Should such instances occur, go to Box 2.

Box 2 recommends that where a lag phase or long term sorption kinetic are observed in the laboratory studies, data points in the field study before 10 mm of rain occur are eliminated and SFO kinetics used to determine DegT50\textsubscript{matrix}. Provided the SFO fit meets the standard quality criteria of FOCUS Kinetics, the resulting DegT50 can be used in the assessment.

If a lag phase or long term sorption kinetic are not observed in the laboratory studies, proceed to Box 3. This fits DFOP kinetics to the normalised data set.

The next step (Box 4) is to check whether the k\textsubscript{fast} and k\textsubscript{slow} rate constants from the DFOP fit are significantly different. This has been set at a pragmatic level of a 5% difference between k\textsubscript{fast} and k\textsubscript{slow}.

No significant difference between k\textsubscript{fast} and k\textsubscript{slow} suggests that SFO kinetics may be describing the decline. If there is no significant difference between k\textsubscript{fast} and k\textsubscript{slow}, use k\textsubscript{slow}. If there is a significant difference between the two DFOP rate constants, go to Box 5 which estimates the DFOP breakpoint.

The breakpoint time is defined as the time when the degradation in the fast degrading compartment is replaced by the degradation in the slow compartment and has to be estimated for DFOP kinetics because the slope of the DFOP curve decreases gradually. According to the EFSA DegT50 opinion, the breakpoint time for DFOP kinetics (t\textsubscript{b}) corresponds with a time equal to three half-lives of the fast-degrading compartment, so g \exp(-k\textsubscript{fast} t\textsubscript{b}) = 0.125 g. The g value corresponds to the proportion of the total mass in the fast degrading compartment. This implies that, at this breakpoint time, 87.5% of the decline of the fast-degrading compartment has taken place. Therefore it is likely that after this breakpoint time, the slow-degrading compartment dominates the overall decline. This is only likely to not be the case for high g values. For example, if g = 0.9 then 0.125 g = 0.11 whereas (1 - g) may still be close to 0.1. In such a case the estimated breakpoint time may be too short. Therefore a check is conducted in Box 6 whether g is below 0.75; if no, it is recommended to apply the HS flow chart (Figure 2) because the estimate of the breakpoint time is not reliable enough. If yes go to box 7.

Box 7 tests whether the cumulative rain is at least 10 mm before or at the estimated breakpoint time. Whilst the time for 10 mm rainfall will have been measured in true time, it is important to compare the estimated breakpoint time (expressed in normalised time) with the time for 10 mm rainfall measured in normalised time. In practice, it is likely to be possible to estimate the normalised time for 10 mm rainfall from the results of the time step normalisation. Alternatively, it may also be estimated by considering the number of samples taken in the field study before 10 mm of rain occurred. Table 1 shows an example of a time series of true and normalised time and the corresponding cumulative rainfall. Let us assume that the breakpoint was found at a normalised time of 2.3 days. Table 1 shows that cumulative rainfall at that time was greater than or equal to 12 mm, so the criterion in box 7 has been fulfilled. Further practical examples on how this is performed will be provided at a later stage.

Table 1: Example of a time series of true and normalised time and corresponding cumulative rainfall

<table>
<thead>
<tr>
<th>True time (days)</th>
<th>Normalised time (days)</th>
<th>Cumulative rainfall (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>12</td>
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<tr>
<td>8</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>20</td>
<td>10</td>
<td>70</td>
</tr>
</tbody>
</table>
If greater than 10 mm of rainfall has not fallen before the break point, $k_{slow}$ has to be rejected because it is too strongly influenced by processes in the top millimetres of the soil. In such a case, go to the Hockey-Stick flow chart because this has an iteration option to use the data after modification. If cumulative rainfall was at least 10 mm at the breakpoint, Box 8 is reached. The problem considered here is that $k_{slow}$ may be not accurate enough, for example because it is based on only a few data points or because the data show considerable scatter. Testing of the accuracy of $k_{slow}$ must be carried out by following procedures identical to those recommended by FOCUS Kinetics. If $k_{slow}$ is accurate enough, the bottom box of the flow chart is reached and $k_{slow}$ can be used. If not, the option is offered to go to the HS flow chart.

If the flow chart in Figure 1 results in a useful $k_{slow}$ then the resulting DegT50 matrix can be calculated as

\[
\ln 2 / k_{slow}
\]

and the rapidly dissipating fraction $F_{field}$ can be calculated from the difference between the initial areic mass $A_0$ and the areic mass at the breakpoint time $t_b$ ($A_{tb}$) according to the following equation:

\[
F_{field} = \frac{A_0 - A_{tb}}{A_0}
\]

$F_{field}$ is used subsequently in exposure calculations to describe the rapidly dissipating fraction at the soil surface. Details of how $F_{field}$ is used will be found in the relevant guidance documents on PEC calculations.

As noted above, there may be reasons why the approach using DFOP kinetics does not offer a robust calculation of DegT50. Therefore the following flow chart using Hockey Stick kinetics can be used.

**Figure 2:** Flow chart for assessment of results of field dissipation studies after analysis with the Hockey-Stick model. The numbers 1 to 3 act as references to the corresponding boxes in the main text. The test of the accuracy in box 3 should be done by following procedures identical to those recommended by FOCUS Kinetics.

Following the time step normalisation and fitting of Hockey Stick kinetics, Box 1 tests whether the cumulative rain is at least 10 mm at the breakpoint time (it is important that the normalised time for
10 mm rainfall to have occurred is used to compare to the breakpoint time which will be in normalised time). If this is not the case, $k_2$ has to be rejected because it is too strongly influenced by processes in the top millimetres of the soil. However, Box 2 offers the option to fix the breakpoint at the time when 10 mm of rain has fallen and to refit both $k_1$ and $k_2$.

If cumulative rainfall was at least 10 mm at the breakpoint, Box 3 is reached. The problem considered here is that $k_2$ may be not accurate enough because it is based on only a few data points or because the data show considerable scatter. Testing of the accuracy of $k_2$ must be carried out by following procedures recommended by FOCUS Kinetics.

If $k_2$ is accurate enough, $k_2$ can be accepted and used. If $k_2$ is not accurate enough, the field study should not be used. It is not considered a problem if $k_1 < k_2$ as site selection should exclude sites where accelerated degradation might occur (i.e. when a substance or related substances have been applied previously at the study site) and because the break point is after 10 mm rainfall $k_2$ will reflect the bulk soil matrix degradation.

If the flow chart in Figure 2 results in a useful $k_2$, then the resulting $DegT50_{matrix}$ can be calculated as

$$\ln(2/k_2)$$

It is only meaningful to calculate the rapidly dissipating fraction $F_{field}$ if $k_1 > k_2$. If this is the case, $F_{field}$ can be calculated on the basis of the difference between the initial areic mass and the areic mass at the breakpoint time $t_b$.

As follows from the guidance above, the values of $k_{fast}$ (DFOP kinetics) and $k_1$ (Hockey Stick kinetics) are not subsequently used in the exposure assessment. These values are not considered reliable because the normalisation process considers only the effect of soil temperature and soil moisture on the degradation rate within the bulk soil matrix which has no meaning for surface losses due to indirect photolysis or volatilisation.

### 2.4. Further quality checks on field derived $DegT50_{matrix}$

The $DegT50_{matrix}$ values estimated using the flow charts in Figures 1 and 2 should be interpreted with consideration of existing information in the registration dossier on the potential for volatilisation and indirect photolysis (see Section 2.2. of the EFSA DegT50 opinion for further details) and the degradation rates from the laboratory soil tests. It is recommended to check whether any of the individual $DegT50_{matrix}$ values are significantly longer ($t$-test at 5% level) than the laboratory $DegT50$ values as described in Appendix A of EFSA (2010). In general, $DegT50_{matrix}$ values from field studies are expected to be shorter than laboratory $DegT50$ values from laboratory studies but the opposite may happen occasionally. The EFSA DegT50 opinion considers it very unlikely that a laboratory study with a certain soil shows a systematically and consistently faster degradation rate than a field study with the same soil at the same temperature and moisture content. It is far more likely that a field $DegT50_{matrix}$ that is significantly longer than the geomean laboratory $DegT50$ is caused by systematic errors in the inverse modelling procedure. It can also happen by coincidence because the number of measured laboratory and field $DegT50$ values may be limited to four values in a dossier. In such a case the magnitude of the effects of conservative assumptions in the inverse modelling procedure should be assessed; if this effect is so large that it may explain the difference with the laboratory $DegT50$ values, then it is considered justifiable to discard the $DegT50_{matrix}$ value of this field study. Please see Section 3.3 of this guidance document for details of how to deal with the situation where field $DegT50$ values are longer than laboratory $DegT50$ values.

The impact of assessing when 10 mm of rainfall has occurred can also influence the calculation of $DegT50$. Spatial variation in daily rainfall may be considerable on a scale of 100 km$^2$. As 10 mm is not a large amount of rainfall, the time needed for 10 mm rainfall since application may show considerable spatial variation at such a scale. Therefore it is advisable to measure cumulative rainfall between soil sampling times at the experimental field or at a distance of less than 1 km; this should be
taken into account in the study protocol for field dissipation studies. In legacy studies, rainfall may not have been measured in available field dissipation studies. In such cases, it is recommended that rainfall data from weather stations no more than 20 km distance from the experimental field should be used. The applicant should make clear that there is no climatological barrier (e.g. mountains or hills; note, this not an exhaustive list of climatological barriers) between the rainfall station and the experimental field.

The proposed procedure only considers the possibility of time-step normalisation. FOCUS Kinetics guidance also describes another normalisation, i.e. rate normalisation. This procedure is based on the principle that the simulated daily transformation rate is corrected for differences between the actual temperature and moisture content and the temperature and moisture content at reference conditions (i.e. 20°C and pF = 2). Following discussions, the Working Group recommended that time-step normalisation was the preferred method for normalisation and that rate constant normalisation should not be conducted. The reasons for this were that rate constant normalisation is a more complex procedure, is less transparent, less intuitive and harder to interpret for many users and appears to offer no real advantage over time-step normalisation.
3. Guidance for estimating model input parameters for the required exposure scenarios

3.1. Background

This chapter describes the selection process for choosing appropriate exposure modelling parameters. Please note that this procedure does not address how to derive modelling parameters where the substance demonstrates a dependence of DegT50 on soil properties such as pH or clay content. It is recommended that in these cases, FOCUS guidance on selection of input parameters is followed.

The purpose is to obtain a median DegT50 for the population of agricultural/ horticultural field soils in the area of use of the substance. So in principle it has to be assessed whether all soils studied can be considered to be part of this population of soils. It is proposed to assess this very pragmatically as follows:

--- exclude studies with volcanic soils because their chemical and physical properties differ substantially from those of temperate mineral soils

--- accept studies with soils from temperate regions outside the EU provided their pH, organic matter and clay contents are within the range of values to be expected for top soils in the EU

--- check for field dissipation studies outside the EU whether temperature and precipitation for the trial site are comparable to those in the EU where the assessed crop is grown.

The main procedures described here detail how to:

i) calculate the geometric means of the laboratory and field degradation rates,

ii) determine whether the databases of laboratory and field degradation rates should be treated separately or combined for the selection of modelling input parameters,

3.2. Calculation of geometric means of laboratory and field DegT50 values

The EFSA DegT50 opinion recommends use of the bias corrected geometric means of degradation rates as input into exposure models. Therefore the first part of the procedure to determine the appropriate soil degradation rate is to determine the bias corrected geometric mean of the laboratory derived database on aerobic DegT50 and the bias corrected geometric mean of the field derived DegT50 values.

Appendix E of this guidance describes a bias-corrected geomean estimator which can be used for this purpose. Appendix E provides a spread sheet that can be used to calculate the bias corrected geometric means of these two separate databases and the allows the necessary comparisons to be made. The background on this calculator is given in Appendix A of EFSA (2010).

3.3. Selection procedure for obtaining modelling endpoints from laboratory and field DegT50 datasets

The second part in the procedure is to determine whether the degradation rates from the separate laboratory and field databases are statistically different. Historically, DegT50 values from field dissipation studies have usually been treated as distinct and ‘higher tier’ from DegT50 values from
laboratory studies as DegT50 from field studies are commonly shorter than those from laboratory studies. The use of separate databases of values in a tiered assessment implies that there must be a clear and valid justification for treating them as distinct databases.

The following flowchart describes the process for deciding whether or not the DegT50 values from laboratory and field dissipation databases can be treated separately.

**Figure 3:** Flow chart for assessment of DegT50 values from laboratory and field dissipation studies. The letters A to E act as references to the corresponding boxes in the main text.

Box A tests whether the geomean laboratory DegT50 is longer than 240 d. If so, there will be on average only 29% decline during the 120 d incubation of the OECD study, making it difficult to measure such low degradation rates. For such persistent substances, it is acceptable not to perform a difference test between laboratory and field but to continue with the field values (i.e. go straight to box D). If the geomean laboratory DegT50 is shorter than 240 d, box B tests the null hypothesis that the geomean DegT50 values from laboratory and field are equal against the alternative hypothesis that the geomean DegT50 from the field is shorter (using the parametric multiplicative shift model described in Appendix E).

If this null hypothesis is not rejected (box C), this guidance recommends pooling all the laboratory and field DegT50 values and calculating the geomean (box F). If the null hypothesis is rejected, then the laboratory studies are discarded and move to box D. In this box it is tested whether at least four field DegT50 values are available for active substance or three for metabolites. The three/four values are based on the data requirement for laboratory DegT50 values in Commission Regulation (EU) No 283/2013 in accordance with Regulation 1107/2009. If this is indeed the case then the geomean field DegT50 is calculated as the endpoint of this flow chart (box E). If less than three/four values are available, more field DegT50 values are requested (box H).
available, it is checked in box G whether the sum of the laboratory and field DegT50 values is at least
four for active substance and three for metabolites. If this is not the case, the uncertainty of the
estimated geometric mean is considered too high and it is proposed to provide more DegT50 values (box H).
If at least three/four values are available this guidance proposes to pool all the laboratory and field
DegT50 values (so back to box F).

Appendix A (section 8.1) of EFSA (2010) gives details of how to assess whether the DegT50 values
from field studies are shorter than those from laboratory studies. The method for determining whether
DegT50 from laboratory and field databases are significantly different uses a value α which is critical
to this comparison. This guidance uses an α value of 25%. In deciding on this value, the Working
Group noted that the α value of 25% is more likely to result in a differentiation between laboratory and
field degradation data sets than lower numerical values of α. It was also noted following consultation
with Member States via the EU Commission Standing Committee on the Food Chain and Animal
Health that there was no clear desire to pursue a more conservative assessment compared to the
practice before this guidance where laboratory and field degradation data sets are treated separately.

As described above, if the outcome of the comparison of laboratory and field databases is that they are
not significantly different, the geometric mean of the combined databases is calculated and used as the input
parameter in exposure modelling; appendix E provides a spreadsheet to calculate the corrected
geometric mean estimator for the median of the sample population. If the laboratory and field datasets
are determined to be significantly different and the geometric field DegT50 is shorter than the geometric
laboratory DegT50, the field derived geometric mean DegT50 value is used.

It is possible that in some cases, the geometric mean field DegT50 is significantly longer than the geometric
DegT50 from laboratory studies. Based on the available knowledge on microbial and chemical
degradation processes of pesticides in soil and based on the review of field tests of simulation models
of persistence by Beulke et al. (2000), it is considered very unlikely that the degradation rate in a
laboratory incubation study with a certain soil (at constant soil moisture and temperature) is
systematically and consistently faster than the degradation rate within the soil matrix in the
agricultural field from which this soil was collected (at the same temperature and moisture content).
Therefore the flow chart in Figure 3 does not test the hypothesis whether the DegT50-field is longer
than the DegT50-lab.

The variation in DegT50 values at pH=2 and 20°C between different soils is very large: EFSA (2010)
compiled available data and found that distributions of DegT50 values have variation coefficients of
about 50%. So in case there are four DegT50-lab values and four DegT50-field values, it may happen
by coincidence that the geometric mean DegT50-field is longer than the geometric DegT50-lab.

In case the DegT50-field values are clearly significantly longer than the DegT50-lab values, it is
recommended not to follow the flow chart of Figure 3 but instead to analyse the reason for this
difference in detail and to decide case by case based on the results of this analysis. This analysis
should also include a critical assessment of the procedures followed in the laboratory studies.
Appendix G provides an example. As described by EFSA(2010; p. 30), it may be justifiable to discard
a DegT50 value obtained from a field study by inverse modelling if it is longer than the DegT50
values obtained from laboratory studies. The justification is that the inverse modelling procedure is not
straightforward and contains a number of assumptions. These may include:

(i) the assumption that the simulation model used for inverse modelling accurately simulated the time
courses of temperature and moisture content of the soil, and
(ii) the assumption that the model parameters accounting for the effect of temperature and moisture on
the degradation rate (i.e. the default Arrhenius activation energy $E_A$ of 65 kJ/mol and the default
moisture exponent B of 0.7) were valid for this combination of soil and substance.

A further justification is that it is in general unlikely that the DegT50 in the soil matrix in field
experiments is longer than in laboratory experiments. If a field DegT50 is longer than the longest
laboratory DegT50, then it should be checked whether the uncertainty in the inverse modelling procedure is so large that it can bridge the gap between this field DegT50 and the longest laboratory DegT50. If the uncertainty is smaller, then the field DegT50 should not be discarded because it is of course possible that the degradation rate for this field soil is by coincidence longer than for any of the other soils studied (populations of DegT50 values have variation coefficients of about 50% so there is a large variation between DegT50 values from different soils).

As described by EFSA (2010) the inversely modelled DegT50 will usually decrease (faster degradation) with increasing $E_A$. The possible effect of using the default $E_A$ of 65 kJ/mol can be checked by repeating the inverse modelling procedure with $E_A = 115$ kJ/mol (i.e. approximately a 95th percentile $E_A$ value). If this leads to a DegT50 that is within the range of the laboratory DegT50 values, the field DegT50 value can be discarded.

As described by EFSA (2010) the inversely modelled DegT50 decreases (faster degradation) with increasing moisture exponent $B$. Often the effect of soil moisture is ignored in the inverse modelling procedure (which corresponds to $B = 0$). The possible influence of ignoring the effect of soil moisture or of using the default $B$ value of 0.7 can be checked by repeating the inverse modelling procedure with values of the exponent $B$ of 1.5 (high value) and 2.9 (extremely high value). If this leads to a DegT50 that is within the range of the laboratory DegT50 value, the field DegT50 value can be discarded.

As described by EFSA (2010), a too high simulated moisture content for the layer in which most of the substance is located, may also lead to a too long inversely modelled DegT50. EFSA (2010, p. 17) also indicated that the numerical models probably overestimate the moisture content of the top millimetres during a drying cycle in the field. This could be checked by simulations with the numerical models using compartment thicknesses of around 1 mm for the top layer: if during most of the field experiment most of the substance remains in the top centimetre of soil and if for more than 75% of the time there are rain-free periods of more than 3 days, then the field DegT50 can be discarded.

If at the end of the procedure it is concluded that field DegT50 values represent degradation within the soil bulk matrix and the field DegT50 are still longer than the lab DegT50, the field and lab datasets should be combined to obtain the geometric mean, as described in box F of figure 3.
REFERENCES


EFSA (European Food Safety Authority), 2014. EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. In prep.


**GLOSSARY AND ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>DegT50</td>
<td>Half-life resulting from transformation of substance in the soil matrix</td>
</tr>
<tr>
<td>FOCUS</td>
<td>Forum for Co-ordination of pesticide fate models and their Use</td>
</tr>
<tr>
<td>PBT</td>
<td>Persistence Bioaccumulation Toxicity</td>
</tr>
<tr>
<td>PEC</td>
<td>Predicted Environmental Concentration</td>
</tr>
<tr>
<td>PECsoil</td>
<td>Predicted Environmental Concentration in soil</td>
</tr>
<tr>
<td>PPP</td>
<td>Plant Protection Product; in the context of this opinion, the term ‘plant protection products’ is used for both the applied formulation and the active substances.</td>
</tr>
<tr>
<td>PPR</td>
<td>Panel Scientific Panel on Plant Protection Products and their Residues</td>
</tr>
<tr>
<td>TWA</td>
<td>Time-Weighted Average</td>
</tr>
<tr>
<td>F</td>
<td>Field rapidly dissipating fraction that is not related to degradation in the soil matrix</td>
</tr>
</tbody>
</table>
A. Information on the test substance

The test substance can be the active substance to be marketed or a transformation product of the test substance for which a field DegT50 is desired.

Usually if transformation products are used as a test substance, they will have reached levels that trigger assessment in appropriate laboratory (lab) soil aerobic, anaerobic or photolysis experiments. These levels and where applicable lab DegT50 triggers for field studies can be found in the legal data requirements of Regulation (EC) No 1107/2009. If reliable transformation DegT50 values can be derived from experiments where precursors in a transformation pathway have been dosed, then the applicant has discretion over whether and for which transformation products they might carry out field experiments, where a transformation product is applied as test substance. Test substance should be prepared / formulated so that it can be evenly applied to a test plot, so that variation in the mass of test substance applied per unit area is minimised. Preparation as a formulation may not be necessary when the test substance is soluble in or miscible with the diluents being employed in the experiment. The formulation does not need to be a typical end use product. End use products that have been used to treat seeds or are ready to use granules should usually be avoided, as the use of these will increase variation in the mass of test substance applied per unit area at the spatial scale of soil core sampling.

The only time a study with an end use product has to be performed (according to legal products data requirements of Regulation (EC) No 1107/2009), is when the test substance is the commercialised formulated active substance and the commercialised formulation technology affects the rate of release of the active substance from the formulation, so would affect the DegT50 that would be estimated for the test substance and kinetic formation fraction that would be estimated for a transformation product.

B. Field plot systems

Test plots should never be cropped at the time of application as this will increase variation in the mass of test substance applied per unit area at the spatial scale of soil core sampling. An experimental design where plots are only maintained bare throughout the experiment has to be followed when plant uptake cannot be excluded as a significant route of dissipation for any of the compounds of interest.

Where robust data is available in the dossier to allow it to be confirmed that crop uptake is not a significant route of dissipation from soil for any of the compounds of interest (for example evidence from following crop metabolism studies), it is an option that both plots maintained bare and plots where grass will germinate be prepared, with parallel experiments being set up on both plot types at each study site. When this option is followed, grassed plots can be seeded after the test substance has been mechanically incorporated (see E.2). Alternatively grassed plots can be pre-seed so the grass crop will emerge after application, when test substance incorporation is to be achieved via irrigation (see E.2.). When results from parallel maintained bare and grass emerged plots are available, soil root zone models should be parameterised for the conditions of the experimental sites, to provide an interpretation of what contribution plant uptake may have made to any difference in DT values between maintained bare and grass emerged plots, as compared to the contribution of plant roots to potentially having enhanced microbially mediated degradation in grass emerged plots. DegT50 should only be derived from the grass emerged plots, when such modelling confirms that plant uptake was not contributing significantly to the DT values estimated from the grass emerged plots.
C. Site selection

As the purpose of these experiments is to obtain a median DegT50 for the population of agricultural / horticultural fields in the area of use of the substance (in the EU), sites can be randomly selected from this population. It is also considered appropriate to use sites located in temperate regions outside the EU provided their pH, organic matter and clay contents are within the range of values to be expected for top soils in the area of use of the substance in the EU. Use of sites with a mineral content derived from volcanic activity where there has been limited pedology, is considered inappropriate because their chemical and physical properties differ substantially from those of temperate mineral soils. For other aspects of site selection consideration of the NAFTA (2006) guidance can be considered. Note, sites with soil characteristics where significant movement of substances of interest out of the microbiially active topsoil layers might occur, should be avoided for experiments used to estimate DegT50. For example sites where soils have course textures combined with low organic carbon, such as the ‘Borstel’ soils typically used in European lysimeter experiments should be avoided.

D. Field plot design

When designing an experiment to estimate DegT50 in topsoil, all processes that can affect the fate of the chemical, except the formation of transformation products or not extracted residues, (such as leaching, volatilisation, soil surface photolysis, runoff and plant uptake) should be minimised as far as possible. Therefore test plots should be level without any slope. See also E.2. for more information on the approaches to be taken to minimise surface processes impacting on the DegT50 estimates. The basic field study design evaluates field degradation in topsoil in bare ground plots or may additionally include plots where grass emerges after application (see B. above), but should exclude the influence of surface processes as far as is practical. The study design should encompass the range of environmental conditions that reflect the actual usage of the test substance, though surface processes should be excluded, even if these might occur as a result of the actual usage. The studies should also include an untreated control plot. Because of field-scale variability, the experimental units in each study should be replicated. The considerations of the NAFTA (2006) guidance regarding replication under D. Field plot design, are considered appropriate. At least four subplots should be used as the basis for the replicated sampling strategy.

E. Procedure

1. Site Characterisation

Consideration of the NAFTA (2006) guidance is considered appropriate (excepting the use of the word dissipation where degradation would be pertinent in this context).

2. Application of the Test Substance

The test substance should be applied to the surface of test plots as evenly as possible, formulated as necessary, as already discussed at A. above. For active substances at least the maximum proposed / intended annual total dose use rate, as will be stated on the label should be used. When necessary the active substance should be applied at a rate greater than the maximum proposed use rate, to ensure that analytical quantification / detection limits for the compounds of interest, enable ≤ 10% / ≤ 5% of initial measured soil residues for the active substance to be quantified respectively. Where the test

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5 The DegT50 may be used as an input parameter for the assessment of leaching to groundwater and surface water. The purpose of the evaluation of the laboratory and field dissipation studies is to obtain a median DegT50 for the population of agricultural/ horticultural field soils in the area of use of the substance (EFSA, 2010, p. 9). In principle it is undesirable to avoid field dissipation studies in which significant leaching occurs because the DegT50 derived from such these studies may contribute in a relevant way to the median DegT50 used for the leaching assessment. However, there is currently no guidance available to derive appropriate DegT50 values from studies in which significant leaching occurs. In principle this is possible using inverse modelling procedures with numerical models but it is impossible to develop such guidance within the given time frame. Therefore it is currently not recommended to use of field studies in which significant leaching occurs.
substance is a transformation product, the application rate should cover at least the maximum formation level expected considering the results of the relevant lab experiments. As for the active substance, when necessary an application rate greater than this should be used when it is necessary to ensure that analytical quantification / detection limits for the compounds of interest enable ≤ 10% / ≤ 5% of initial measured soil residues to be quantified respectively.

Recommended equipment for pesticide delivery to experimental plots should be of high precision, suited for the particular pesticide formulation (some pesticides may need to be homogenised by a continuous mixing device in the tank) and fitted with a device to keep drift loss to a minimum.

Only a single application should be made to each test plot. The applied mass per surface area should be measured in parallel in two ways. The first is based on measurements of (i) the speed of the spray boom or other application method, (ii) the flow rate of the liquid from the nozzles or other flow rate, (iii) the concentration of the pesticide in the diluent. The second is based on measurements of deposition of pesticide on the soil surface (e.g. spray cards). The results of these two estimates of the applied mass per surface area should be compared with the mass per surface area recovered from the soil sampled at the day of application.

Following application, one of the following procedures should be employed to minimise the impact of surface processes (e.g. photolysis, volatilisation) on the DegT50 that can be estimated for each test plot.

- incorporation of the substance in the soil immediately after spraying to the soil surface, mixing should be at least over a depth of 10 cm. A plot power harrow can be used for this with most soil textures.
- injection of the substance within the top layer (0 – 30 cm) of the soil, followed by mixing through the soil over a depth of at least 10 cm. Again a plot power harrow can be used to achieve this.
- irrigation immediately after application of the substance to the soil surface; the irrigation volume should be sufficient to reach an average penetration depth of the substance of 10 mm (to be calculated with models such as PELMO and PEARL).
- Even application of a 1 cm deep layer of sand to the soil surface, note this approach should not be used where any of the substances of interest have a vapour pressure > 1x10^-4 Pa. (the function of this vapour pressure limit for this study design, is to exclude that the process of volatilisation is a significant factor in the DT value that can be estimated, particularly in relation to earlier sampling times). Observations should be made and recorded to confirm that the sand layer remained in place until at least 10mm of rainfall / irrigation has occurred.

In all cases, the first soil sampling should take place after the incorporation, irrigation or covering has taken place.

3. **Study Duration**

Studies should continue until the concentration of test substance has reached ≤ 10% of initial measured test substance in the target top 10cm soil layer or the transformation products of interest formed from the test substance have peaked and subsequently declined such that they no longer account for more than 10% of the molar mass of the initial mass of the test substance. Movement out of the top 10cm soil layer does not invalidate the study for the purpose of calculating DegT50 and 90s.

4. **Management**

Consideration of the NAFTA (2006) guidance is considered appropriate, except tillage operations before application should ensure an even fine seed bed type tilth is achieved over at least the top 15cm
of soil and that any cultivation incorporating the substance after application results in even incorporation over at least the top 10cm soil layer.

5. Irrigation

Treated plots that are maintained bare do not usually require irrigation except when, this is the strategy used to move the test substance into the soil immediately after application (see 2. above for further details). Some soil textures (for example where there is a high clay content) may benefit from irrigation during prolonged dry periods to facilitate the sampling of intact soil cores. Irrigation for this purpose is appropriate. The irrigation amounts applied should aim to keep soil moisture contents in the top 30cm below field capacity, so substances of interest remain within the microbially active topsoil. When plots have grass cover, irrigation to sustain the grass is appropriate. Again the irrigation amounts applied should aim to keep soil moisture contents in the top 30cm below field capacity.

6. Environmental Conditions and Monitoring

Consideration of the NAFTA (2006) guidance is considered appropriate, except the use of tracers to track the potential depth of leaching is not pertinent, as the study design should minimise the potential for substances to leach from the upper soil layers. It is advised that best practice is for the daily average soil temperatures that have to be measured, to be determined at a depth of 10cm.

7. Soil Sampling

Consideration of the NAFTA (2006) guidance is considered appropriate, though references to DT75 should be replaced by DT90 in the context of the EU data requirements. Soil sampling should usually proceed to a depth of at least one metre. Depth segments should continue to be analysed until the depth is reached, where a segment no longer contains the compounds of interest above the limit of detection for the analytical method. Time intervals chosen for sampling should be based on the results of lab studies and other field studies, if available. Sampling frequency should consider lab DegT estimates with increased frequency of sampling for shorter DegT50 compounds. The number and distribution of sample times should also be sufficient to adequately characterise the formation and decline of the transformation products of interest. A minimum of 8 time intervals should be sampled. Significantly more sampling times than this may be required when a number of transformation products are of interest and kinetic fitting of both formation and decline of these needs to be determined.

It is recommended to divide the experimental plots into at least four subplots and to take randomly, at least 10 samples from each subplot. The diameter of the sampling core should be at least 5 cm. It is important that NAFTA (2006) guidance E.7.f. on the handling of samples is adhered to. All samples from one subplot and the same depth segment may be mixed before analysis.

It is unacceptable that all samples from the plot for each depth segment are mixed into one sample because it is essential for the DegT50 inverse modelling procedure that there is information on the uncertainty of the measured residue at each sampling time. This allows measured time points with a large uncertainty to be allocated a lower weight in the inverse modelling procedure than measured time points with a small uncertainty (e.g. often the scatter immediately after application is larger than at later sampling times).

The total mass of moist soil from each mixed sample should be recorded because it is the intention to assess the mass per surface area present in each depth segment (soil layer). If this mass of moist soil is not measured and recorded, the mass per surface area can only be calculated after the bulk density of the soil has been estimated. This estimation may be inaccurate. This inaccuracy can be avoided simply by measuring and recording the total mass of moist soil of each mixed sample. For each mixed sample, the mass of substance per sampled surface area should be calculated from the content of substance in the soil, the total mass of soil in the sample, and the sampled surface area. Results from all depth segments containing detectable residues for the compound(s) of interest should be used when estimating DegT50 values. Therefore a final manipulation of the results has to be completed. The
masses per surface area of the different depth segments from the same subplot have to be summed up to give for each subplot, the total mass per surface area. These total masses per surface area form the basic data for the further DegT50 estimation.

8. **Sampling of Other Media**

Consideration of the NAFTA (2006) is considered appropriate, though plant material sampling, air sampling and sampling of runoff are not relevant for DegT50 experiments.

9. **Sampling Strategies to Increase Sensitivity**

Consideration of the NAFTA (2006) is considered appropriate, though plant material sampling, air sampling and sampling of runoff are not relevant for DegT50 experiments.

10. **Handling and analysis of samples**

Consideration of the NAFTA (2006) section E.7.f. and Appendix III is considered appropriate, though the following additional recommendations should be followed:

As the efficiency of the sample extraction procedure used influences the DegT50 that is calculated from the experiment (more efficient extraction procedures, will usually result in longer DegT50 being estimated), adequate and consistent extraction procedures should be followed for all samples taken at a trial site. It is desirable that the same extraction procedure(s) be used in all field and laboratory DegT50 experiments in a dossier. Whilst this will not be the usual situation, particularly for substances that have regulatory data bases that have been developed over many years, it is preferable that similar extraction procedure(s) be used in new field DegT50 experiments to those that have been used in the laboratory soil incubations and already available soil field experiments.


[http://www.epa.gov/oppefed1/ecorisk_ders/terrestrial_field_dissipation.htm](http://www.epa.gov/oppefed1/ecorisk_ders/terrestrial_field_dissipation.htm)
Appendix B. Use of geomean Kom or Koc

The Panel proposed to use a CV of 0.5 and a lognormal distribution for the Kom or Koc

As described in Section 4.2.5 of EFSA (2012). The reason for not using the normal distribution is that the variable (Kom) has only positive values, but its use with such a large CV would give a high probability of negative values. The scenario-selection procedure in Chapter 4 of EFSA (2012) was based on the assumption that median substance properties will be derived from the dossiers as input parameters for the scenario calculations. The FOCUS guidance in place up to publication 2012 was to use an arithmetic mean Kom or Koc if less than nine values were available and the median Kom or Koc of the sample if nine or more were available (Anonymous, 2012, p. 26). For a lognormal distribution, the arithmetic mean is not an estimator for the median, whereas the geomean Kom or Koc can be so used.

The geomean as an estimator of the median of the population also has better properties as the median of the sample, and hence this is the recommendation for all sample sizes greater than the minimum required by the data-requirements. As indicated in appendix A of EFSA (2010) the median of the population can best be estimated with the following bias-corrected geomean estimator. A bias-corrected geomean estimator of the median of the population is:

\[ K_{om,geo} = \exp \left( \frac{-\sigma^2}{2N} \sum_{n=1}^{N} \ln(K_{om,n}) \right) = \exp \left( \frac{-\sigma^2}{2N} \left( \frac{1}{N} \sum_{n=1}^{N} \ln(K_{om,n}) \right) \right) \]

where \( K_{om,n} \) is the \( n^{th} \) Kom value, \( \sigma \) is the standard deviation of the logarithms of the \( K_{om} \) values, and \( N \) is the sample size (total number of \( K_{om} \) values). The standard deviation \( \sigma \) is estimated with:

\[ \mu = \frac{1}{N} \sum_{n=1}^{N} \ln(K_{om,n}) \]

\[ \sigma = \sqrt{\frac{1}{N-1} \sum_{n=1}^{N} (\ln(K_{om,n}) - \mu)^2} \]

So if there are four \( K_{om} \) or \( K_{oc} \) values 30, 52, 87 and 101 L kg\(^{-1}\) then \( \sigma \) as calculated with Eqn 2 is 0.55 and the bias-corrected geomean (Eqn 1) gives 58.6 L kg\(^{-1}\) whereas the arithmetic mean is 67.5 L kg\(^{-1}\) and the classic geomean is 60.8 L kg\(^{-1}\). The arithmetic mean again gives higher estimates of the median, which is a general characteristic of these means. For small sample sizes (e.g. four \( K_{om} \) or \( K_{oc} \) values in a dossier), the geomean and the arithmetic mean may differ by tens of percents. The same may apply to the difference of the geomean and the median of the sample as the above example shows.

The recommendation to use the bias corrected geomean \( K_{om} \) or \( K_{oc} \) does not only apply to the soil exposure assessment but also to other exposure assessments (e.g. leaching to groundwater and to surface water) because the PPR Panel did not see any rationale of using an arithmetic mean for a quantity that is better described with a lognormal distribution. The FOCUS recommendation to use the arithmetic mean of the Freundlich coefficient (1/n) from the available reliable adsorption studies in modelling calculations is maintained. This is because this parameter has a population that is expected to be normally distributed.

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6 Very rarely, substances such as anions may have a small negative \( K_d \) and for these the concept of \( K_{om} \) cannot be applied.
Appendix C. Crop Interception factors

EFSA decided to launch a procurement and a grant activity to collect scientific information on crop interception and to evaluate the crop interception values proposed by FOCUS. Interception by crops reduces the amount of the plant protection product that reaches the ground underneath the crop. At some steps / tiers of exposure assessment only the plant protection product that reaches the ground are taken into account in regulatory calculations of predicted environmental concentrations (PECs) in soil, surface water and groundwater (for groundwater this is the case at the first tier). It is important that the crop interception factors used in the regulatory risk assessment are based on well-documented data and in that way act as robust and representative values.

In a procurement activity a literature review on cereals resulting in a database and a report were prepared by van Beinum and Beulke (2010). The proposals for the crop interception values for cereals were revised by the PPR Panel in an Opinion (EFSA, 2012). In a subsequent grant activity a literature review on other FOCUS crops resulted in a database and a report prepared by Olesen and Jensen (2013). Both reports are published on the EFSA website. The above mentioned reports and the Opinion resulted in the updating of the FOCUS crop interception values as set out in the tables below (table numbers are those of the pertinent FOCUS version control documents). Note in the tables below, the rounding criteria of Olesen and Jensen (2013) have been applied to the PPR Panel Opinion (EFSA, 2012) cereal values.

Ground water

**Table 1.4:** Interception (%) by apples, bushberries, citrus and vines dependent on growth stage.

<table>
<thead>
<tr>
<th>Crop</th>
<th>Stage</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apples</td>
<td>without leaves 50</td>
<td>flowering 60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>foliage development 70</td>
</tr>
<tr>
<td>Bushberries</td>
<td>without leaves 40</td>
<td>flowering 60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>flowering 60</td>
</tr>
<tr>
<td>Citrus</td>
<td></td>
<td>all stages 80</td>
</tr>
<tr>
<td>Vines</td>
<td>without leaves 40</td>
<td>first leaves 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>leaf development 60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>flowering 60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ripening 75</td>
</tr>
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</table>
Table 1.5: Interception by other crops dependent on growth stage

<table>
<thead>
<tr>
<th>Crop</th>
<th>Bare – emergence</th>
<th>Leaf development</th>
<th>Stem elongation</th>
<th>Flowering</th>
<th>Senescence Ripening</th>
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<tr>
<td></td>
<td>00 - 09</td>
<td>10 - 19</td>
<td>20 - 39</td>
<td>40 - 89</td>
<td>90 - 99</td>
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<td>Beans (field + vegetable)</td>
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<td>70</td>
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<td>Carrots</td>
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<td>50</td>
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<td>Oil seed rape (summer)</td>
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<td>Oil seed rape (winter)</td>
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<td>85</td>
</tr>
<tr>
<td>Potatoes</td>
<td>0</td>
<td>15</td>
<td>60</td>
<td>85</td>
<td>50</td>
</tr>
<tr>
<td>Soybean</td>
<td>0</td>
<td>35</td>
<td>55</td>
<td>85</td>
<td>65</td>
</tr>
<tr>
<td>Spring cereals</td>
<td>0</td>
<td>0</td>
<td>BBCH 20-29</td>
<td>BBCH 30-39</td>
<td>BBCH 40-69</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Strawberries</td>
<td>0</td>
<td>30</td>
<td>50</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Sugar beets</td>
<td>0</td>
<td>20</td>
<td>70 (rosette)</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>Sunflower</td>
<td>0</td>
<td>20</td>
<td>50</td>
<td>75</td>
<td>90</td>
</tr>
<tr>
<td>Tobacco</td>
<td>0</td>
<td>50</td>
<td>70</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>0</td>
<td>50</td>
<td>70</td>
<td>80</td>
<td>50</td>
</tr>
<tr>
<td>Winter cereals</td>
<td>0</td>
<td>0</td>
<td>BBCH 20-29</td>
<td>BBCH 30-39</td>
<td>BBCH 40-69</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

* The BBCH code is indicative (BBCH, 1994).
** A value of 90 is used for applications to established turf
* BBCH code of 20-29 for tillering and 30-39 for elongation
Surface water Step 2

**Table 2.4.2-1:** Step 2: crop interception

<table>
<thead>
<tr>
<th>crop</th>
<th>no interception</th>
<th>minimal crop cover</th>
<th>intermediate crop cover</th>
<th>full canopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBCH-code *</td>
<td>00 – 09</td>
<td>10 – 19</td>
<td>20 – 39</td>
<td>40 – 89</td>
</tr>
<tr>
<td>Cereals, spring and winter</td>
<td>0</td>
<td>0</td>
<td>0.2</td>
<td>0.7</td>
</tr>
<tr>
<td>Citrus</td>
<td>0</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>Cotton</td>
<td>0</td>
<td>0.3</td>
<td>0.6</td>
<td>0.75</td>
</tr>
<tr>
<td>Field beans</td>
<td>0</td>
<td>0.25</td>
<td>0.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Grass / alfalfa</td>
<td>0</td>
<td>0.4</td>
<td>0.6</td>
<td>0.75</td>
</tr>
<tr>
<td>Hops</td>
<td>0</td>
<td>0.2</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Legumes</td>
<td>0</td>
<td>0.25</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Maize</td>
<td>0</td>
<td>0.25</td>
<td>0.5</td>
<td>0.75</td>
</tr>
<tr>
<td>Oil seed rape, spring and winter</td>
<td>0</td>
<td>0.4</td>
<td>0.7</td>
<td>0.75</td>
</tr>
<tr>
<td>Olives</td>
<td>0</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Pome / stone fruit, early and late</td>
<td>0</td>
<td>0.2</td>
<td>0.4</td>
<td>0.65</td>
</tr>
<tr>
<td>Potatoes</td>
<td>0</td>
<td>0.15</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Soybeans</td>
<td>0</td>
<td>0.2</td>
<td>0.5</td>
<td>0.75</td>
</tr>
<tr>
<td>Sugar beet</td>
<td>0</td>
<td>0.2</td>
<td>0.7</td>
<td>0.75</td>
</tr>
<tr>
<td>Sunflower</td>
<td>0</td>
<td>0.2</td>
<td>0.5</td>
<td>0.75</td>
</tr>
<tr>
<td>Tobacco</td>
<td>0</td>
<td>0.2</td>
<td>0.7</td>
<td>0.75</td>
</tr>
<tr>
<td>Vegetables, bulb</td>
<td>0</td>
<td>0.1</td>
<td>0.25</td>
<td>0.4</td>
</tr>
<tr>
<td>Vegetables, fruiting</td>
<td>0</td>
<td>0.25</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Vegetables, leafy</td>
<td>0</td>
<td>0.25</td>
<td>0.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Vegetables, root</td>
<td>0</td>
<td>0.25</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Vines, early and late</td>
<td>0</td>
<td>0.4</td>
<td>0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Application, aerial</td>
<td>0</td>
<td>0.2</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Application, hand</td>
<td>0</td>
<td>0.2</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>(crop &lt; 50 cm and &gt; 50 cm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No drift (incorporation /seed treatment)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*NOTE: indicative, adapted coding, the BBCH-codes mentioned do not exactly match (BBCH, 1994).
Appendix D. GUIDANCE FOR SUBSTANCE PROCESSES ON THE CROP SURFACE

Appendix C provided guidance on crop interception percentages for different crops as a function of the development stage. EFSA (2012) considers it not defensible to assume that substance molecules intercepted by the crop will never reach the soil. The background is that there is insufficient evidence that wash off can be ignored under all relevant circumstances. Therefore it is necessary to include simulation of the behaviour of parent substances on crop surfaces in all exposure assessments in which these crop interception percentages are used.

Most numerical models include a first-order dissipation process for substance residue on the crop surface. This dissipation is the combined result of penetration into the plant and degradation processes (e.g. photolysis) on the plant surface (volatilisation losses may be simulated separately by the numerical models so these are not included). Based on EFSA (2012; section 7.7.2) it is recommended to use a default half-life for this foliar dissipation of 10 days. This default value may be overruled by experiments with the substance considered and the crop under a range of relevant conditions.

Wash-off of plant residues of plant protection products by rainfall is described in most numerical models with:

\[ R = w q m_a \]

Where:

- \( R \) is the rate of wash off of mass of substance per field area (mg dm\(^{-2}\) d\(^{-1}\))
- \( w \) is the wash-off factor (mm\(^{-1}\))
- \( q \) is the rainfall rate (mm d\(^{-1}\))
- \( m_a \) is the mass of substance per field area on the plant surface (mg dm\(^{-2}\)).

Based on EFSA (2012) it is recommended to use as a default value \( w = 0.1 \) mm\(^{-1}\). This will lead to wash off of about 10% of the mass of substance remaining on the plant surface by every millimetre of rainfall. This default value can be overruled by results of wash-off experiments with the plant protection product considered. Such experiments should not be carried out with the pure active substance but with relevant formulated products, because the presence of co-formulants in the formulation can affect the wash-off characteristics of the active substance. Studies should also be performed on the proposed crops because different leaf surfaces can influence wash-off characteristics.

For the current numerical exposure models, when used in groundwater and soil exposure assessments, it is essential that the dose at application is divided between the residue intercepted by the crop and the substance deposited on the soil surface. The division of the dose between plant surface and soil is determined by the appropriate crop interception factors described in Appendix C.

For the numerical models when used for groundwater and soil exposure assessment that do not already have the capacity for this division of the dose between both canopy and soil to be implemented, it is recommended that they be updated to enable this.
Appendix E. EFSA DegT50 and Sorption Endpoint Selector

See attached Excel sheet (Appendix E EFSA DegT50 and Sorption Endpoint Selector).
Appendix F. Worked example of faster degradation in field than in lab

In this example, seven DegT50 for the active substance were derived from dark aerobic soil degradation studies in the laboratory. Kinetic fitting was performed in agreement with Focus (2006). The corresponding range of DegT50 values derived, after normalisation to FOCUS reference conditions, was 67 to 221 days with a corrected geomean (calculated using the “Efsa DegT50 and Sorption Endpoint Selector”) of 107.9 days (Table 2).

In addition, eight field studies not tailored for DegT50 (legacy studies) were also available. The field soil dissipation studies available were performed in Germany, Spain, UK, and France. Following the framework presented in this guidance, six of these field studies could be used to calculate the DegT50 in soil.

For the six field studies used to calculate DegT50, data relating to applied dose to the soil surface, daily temperatures, daily soil moisture conditions, and daily rainfall (including the date when 10 mm rainfall has fallen) were available in the study reports, as presented in Table 1. Scrutiny of the data suggested that 6 to 11 points would still be available after 10mm rainfall had fallen to elaborate kinetic fittings for deriving DegT50.

Table 1: Characteristics of the field dissipation studies

<table>
<thead>
<tr>
<th>Field study</th>
<th>Remarks</th>
<th>Daily temp.</th>
<th>Daily soil moist.</th>
<th>Daily rainfall</th>
<th>App. Season</th>
<th>Total samples</th>
<th>Samples after 10 mm rainfall</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Spring</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Spring</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Summer</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>-</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>Summer</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Spring</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>Multi-application</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Summer</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Long-term study</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Spring</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>Long-term study</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Spring</td>
<td>10</td>
<td>8</td>
</tr>
</tbody>
</table>

In agreement with the proposed guidance, the six remaining field study datasets were normalised to FOCUS reference conditions using time-step normalisation (using the procedure as describe in Section 2.3.2).

Following the flow chart for assessment of results of field dissipation studies after analysis with the DFOP model as presented in Figure 1, kf ast and ks low were found to be different by at least 5%. Following calculation of the DFOP ‘breakpoint’, it was found that the breakpoint occurred after >10mm rainfall. The assessment subsequently showed that ks low was considered accurate enough and used to derive DegT50 for field studies.

Resulting field DegT50 values ranged from 26 to 75 days with a corrected geomean of 42.2 days derived from the Efsa DegT50 and Sorption Endpoint Selector (Table 3).

Tables 2 and 3: Active substance laboratory and field DegT50

<table>
<thead>
<tr>
<th>Active Substance</th>
<th>Laboratory DegT50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soils DT50 (days) at 20°C and pF2</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>112</td>
</tr>
<tr>
<td>2</td>
<td>134</td>
</tr>
<tr>
<td>3</td>
<td>124</td>
</tr>
<tr>
<td>4</td>
<td>86</td>
</tr>
<tr>
<td>5</td>
<td>78</td>
</tr>
<tr>
<td>6</td>
<td>67</td>
</tr>
<tr>
<td>10</td>
<td>221</td>
</tr>
<tr>
<td>Corrected geomean (Efsa DegT50 and Sorption Endpoint Selector)</td>
<td>107.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Active Substance</th>
<th>Field DegT50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soils DT50 (days) at 20°C and pF2</td>
<td></td>
</tr>
<tr>
<td>a</td>
<td>59</td>
</tr>
<tr>
<td>b</td>
<td>41</td>
</tr>
<tr>
<td>c</td>
<td>39</td>
</tr>
<tr>
<td>d</td>
<td>54</td>
</tr>
<tr>
<td>e</td>
<td>75</td>
</tr>
<tr>
<td>f</td>
<td>26</td>
</tr>
<tr>
<td>g</td>
<td>26</td>
</tr>
<tr>
<td>Corrected geomean (Efsa DegT50 and Sorption Endpoint Selector)</td>
<td>42.2</td>
</tr>
</tbody>
</table>

According to the flow chart for assessment of DegT50, since the corrected geomean from laboratory DegT50 were shorter than 240 days at 20°C, the procedure to determine whether the degradation rates from the separate laboratory and field databases are statistically different can be undertaken (Figure 3).

The null hypothesis H0 “DegT50-field = DegT50-lab” was tested against alternative hypothesis Ha “DegT50-field < DegT50-lab”. In this example, the Efsa DegT50 and Sorption Endpoint Selector indicated that the test confirms that field studies show shorter DegT50 that laboratory studies. The null hypothesis H0 “DegT50-field = DegT50-lab” is then rejected. This result indicates that the degradation in the field proceeded statistically significantly faster than in the laboratory studies (alpha level: 25 %). According to the flow chart (Figure 3), since at least 4 field DegT50 values were available for the active substance, it is recommended to “use the geomean of field DegT50” of 42.2 days.

Information on degradation in laboratory and field was also available for two metabolites that are both formed from the parent substance (metabolite 1 and metabolite 2). The same approach as presented above in the Table 1 for the active substance was also followed for both metabolites to determine the accuracy of the existing field studies not tailored for DegT50 (legacy studies).

For metabolite 1, only two laboratory DegT50 values (303 and 134 days respectively) were derived in dark aerobic soil degradation studies in the laboratory (after normalisation to FOCUS reference conditions and according to Focus, 2006), Table 4. In addition, a total of 5 field studies were also
made available for the same compound (M1). Resulting DegT50 values were in the range of 24 days to 86 days (with a corresponding corrected geomean calculated using the Efsa DegT50 and Sorption Endpoint Selector of 44 days, Table 5.

For the metabolite 2, again only two laboratory DT50 were available showing fast degradation (DegT50 after normalisation 0.6 days and 1.5 days). In addition a single DegT50 (1.9 days) was derived from the field.

**Tables 4 and 5: Metabolites laboratory and field DegT50**

<table>
<thead>
<tr>
<th>Metabolites</th>
<th>Laboratory DegT50 (days) at 20˚C and pF2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soils</td>
<td>Metabolite 1</td>
</tr>
<tr>
<td>1</td>
<td>303</td>
</tr>
<tr>
<td>2</td>
<td>135</td>
</tr>
<tr>
<td>Corrected geomean estimator for the median(from PPR Fate Calculation boxes)</td>
<td>186</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metabolites</th>
<th>Field DegT50 (days) at 20˚C and pF2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soils</td>
<td>Metabolite 1</td>
</tr>
<tr>
<td>a</td>
<td>48</td>
</tr>
<tr>
<td>b</td>
<td>24</td>
</tr>
<tr>
<td>c</td>
<td>47</td>
</tr>
<tr>
<td>d</td>
<td>58</td>
</tr>
<tr>
<td>e</td>
<td>86</td>
</tr>
<tr>
<td>Corrected geomean estimator for the median(from PPR Fate Calculation boxes)</td>
<td>47.5</td>
</tr>
</tbody>
</table>

According to the flow chart for assessment of DegT50, since corrected geomean from laboratory DegT50 were shorter than 240 days at 20˚C, the procedure to determine whether the degradation rates from the separate laboratory and field datasets are statistically different can be performed (Figure 3).

For metabolite 1, the null hypothesis H0 “DegT50-field = DegT50-lab” was tested against alternative hypothesis Ha “DegT50-field < DegT50-lab”. The Efsa DegT50 and Sorption Endpoint Selector indicated that the test confirms that field studies show shorter DegT50 than laboratory studies. The null hypothesis H0 “DegT50-field = DegT50-lab” is rejected. According to the flow chart (Figure 3), since in total at least 3 field DegT50 values for metabolite 1 were available, it is recommended to “use the geomean of field DegT50” of 47.5 days.

Then, for metabolite 2, the null hypothesis H0 “DegT50-field = DegT50-lab” was tested against alternative hypothesis Ha “DegT50-field < DegT50-lab”. In this example, the Efsa DegT50 and Sorption Endpoint Selector indicated that the single value does not contradict the hypothesis that it is a result from the distribution of laboratory values. The null hypothesis H0 “DegT50-field = DegT50-lab” is not rejected. This result indicates that the dissipation in the field does not proceed significantly faster statistically than the results of the laboratory studies (alpha level: 25 %). According to the flow
chart (Figure 3), the recommendation is to “use the geomean of lab and field DegT50 values” of 1.1 days (calculated using both lab values of 0.6; 1.9 days and single field value of 1.5 days).
Appendix G. Worked example of slower degradation in field than in lab

This appendix describes an example of a substance Sub₁ (an insecticide) that showed much slower dissipation in field soil after spraying onto bare soil than expected from the laboratory DegT50 studies.

The range of DegT50 values measured in dark aerobic soil degradation studies in the laboratory (after normalisation to FOCUS reference conditions using the Q10 default of 2.58) was 18 to 90 days with a geometric mean of 25 days (four soils with organic matter contents between 1.5 and 2.5%). The initial content in soil of Sub₁ in these studies was 1 mg/kg.

There were field soil dissipation studies available in which Sub₁ was sprayed on bare soil at four sites across the EU at a rate of 0.25 kg/ha as an emulsifiable concentrate in a volume of water of 500 L/ha. The organic matter content of the top soil layers ranged from 1.5 to 2.5%. The results of these field dissipation studies were normalised to FOCUS reference conditions and resulting first-order DegT50 values ranged from 130 to 400 days with a geometric mean of 200 days.

These results indicate that the dissipation in the field proceeded significantly slower statistically than expected on the basis of the laboratory studies. The question is then what the possible cause of this is because it is very unlikely that the degradation rate in a field soil is much slower than in a sample taken from this soil and transferred to the laboratory.

The $K_{Foc}$ value of Sub₁ ranged from 15000 to 70000 L/kg in studies with five soil with a geometric mean of 41000 L/kg. This geometric mean corresponds with a $K_{om}$ of approximately 24 000 L/kg. The water solubility of Sub₁ is 0.06 mg/L at 20°C. Its vapour pressure is low (<1 µPa at 20°C). Sub₁ does not dissociate between pH 2 and 8. A laboratory study on soil photolysis showed a DegT50 of about 150 d in dry soil for sunlight conditions at latitude 40° N.

Let us consider what happens with Sub₁ in the field. As described above, it was sprayed at a rate of 0.25 kg/ha in a water volume of 500 L/ha. A volume of 500 L with Sub₁ at its water solubility contains 30 mg of Sub₁, i.e. 0.00003 kg. Therefore the concentration of Sub₁ in the spraying tank is approximately four orders of magnitude higher than its water solubility.

Spraying of 500 L water per ha corresponds to a water layer of 0.05 mm (1 mm is 10 000 L/ha). This will penetrate 0.2 mm into the soil (so essentially it is a thin film on the soil surface in the form of fine droplets). Evaporation rates in summer are typically 5 mm/d in southern Europe in summer. Therefore this water layer will evaporate usually within a fraction of an hour. This gives a concentration of Sub₁ in the top 0.2 mm in the order of 50-100 mg/kg. Assuming sorption equilibrium, 2% organic matter and a $K_{om}$ of 24 000 L/kg, gives then a concentration in the water phase of 0.1-0.2 mg/L, thus exceeding the water solubility. In view of the application as an emulsifiable concentrate this assumption of sorption equilibrium is not defensible. It is more likely that Sub₁ is still encapsulated in some solid form in the dried remnants of the formulation.

Sub₁ has first to dissolve before it can enter into the soil. Assuming a dissolution concentration at 50% of the water solubility of 0.06 mg/L and a dose of 0.25 kg/ha, it will require some 800 mm of rainfall to dissolve the dose completely. After dissolution, movement of Sub₁ will be slow in soil; assuming piston flow, 2% organic matter, a $K_{om}$ of 24 000 L/kg and a dry bulk density of 1 kg/L it can be estimated that Sub₁ moves only 0.2 mm through soil for each 100 mm of rainfall penetrating into the soil. In reality the movement is expected to be somewhat faster because of dispersion in the solute transport in soil.

Therefore the slow dissipation of Sub₁ in the field studies was not caused by slow degradation in the soil matrix but by slow dissolution from the top millimetre of soil (and perhaps also some photochemical degradation in the top millimetre of soil), followed by slow penetration into the soil matrix.
The laboratory studies were conducted at an initial content of 1 mg/kg. Assuming sorption equilibrium, 2% organic matter and a $K_{om}$ of 24,000 L/kg, gives then a concentration in the water phase of 0.0025 mg/L which is an order of magnitude lower than the water solubility of 0.06 mg/L at 25°C. Therefore this dissolution process was unlikely to significantly influence the results of the laboratory studies. Thus the main difference between the lab and the field was that in the lab the substance was mixed through soil at 1 mg/kg whereas in the field spraying onto bare soil led to a concentration of 50-100 mg/kg (in a very thin top layer) which could only dissolve slowly.

The aim of the guidance is to assess the degradation rate within the soil matrix. However, these field dissipation studies do not provide information about this degradation rate. Therefore it depends on the type of exposure assessment whether this field dissipation study contains relevant information. For example, for the groundwater leaching assessment it would be advisable to ignore this information because Sub$_1$ is likely to degrade relatively quickly in soil after it has penetrated e.g. below 1 cm depth in soil. However, if a leaching model could be used that includes dissolution of the dose as a process, these studies could be used to calibrate the dissolution parameters in this model. The field dissipation study may also be relevant if the effects on soil organisms such as Collembola need to be assessed which live predominantly in the top few millimetres of the soil.